review by the Examiner since it deals with issues already considered by the Examiner. The claims, if amended as proposed, do not present new issues requiring further consideration or search. Also, the amendment introduces no new matter into the application. Support for the amendment to define the inactivated *Sarcocystis neurona* cells as being chemically-inactivated is found on page 9, lines 23-29 of the specification. Support for new Claims 26-29 relevant to the specific antigens isolated from the deposited source is found in the description of the isolate SNg on page 8, lines 4-9 and elsewhere in the specification showing how to use the immunogenically active component of the invention in a formulated vaccine.

Applicants gratefully acknowledge that the Examiner has kindly withdrawn several of the previous objections and rejections as set forth on page 3 of the Office action. In order to resolve the remaining issues, it is hoped that the Examiner will enter the present amendment, albeit after a final rejection, and consider the amended claims in a positive light. It had been believed that the prior arguments would suffice to overcome the rejections of record. Since the Examiner was not persuaded to allow the claims, this amendment is now deemed necessary to convince the Examiner that the claimed invention is distinguishable from the cited art without any doubt. Entry and consideration of the claims, as amended, are therefore respectfully requested at this time.

The Examiner maintains the rejection of Claims 1, 2, 4-8 and 10-14 (now Claims 1, 4-8, 10, 11, 13 and 14) under 35 U.S.C. § 112, first paragraph, for reasons given on pages 3-6 of the Office action. The Examiner has kindly clarified the rejection explaining that it is based on a problematic scope of enablement, not a complete lack of enablement. She finds that the claims are enabled for the inducing of *S. neurona* specific neutralizing antibodies with inactivated merozoite whole cells. Although Applicants respectfully disagree with the merits of the rejection, Claims 1, 4-8, 10, 11, 13 and 14 have been amended to conform to the permissible scope of the whole cells to expedite matters. In view of the amendment, it is respectfully requested that the Examiner withdraw the rejection.

The Examiner objects to Claims 1, 2, 4-8 and 10-14 for reciting non-elected inventions. This objection is rendered moot by the present amendment that revises these claims to set forth the invention under examination. To advance prosecution towards an immediate allowance, the amendment cancels without prejudice the non-elected subject matter from the application with

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one minor exception. Withdrawn method Claims 18, 19, 21 and 22 have been retained and amended to include the same limitations as the product claims in the event the Examiner allows the product claims and permits rejoinder of the corresponding method claims. Applicants reiterate the right to file a divisional directed to the non-elected subject matter of the claims in due course.

The Examiner maintains the rejection of Claims 1, 2 and 4-8 (now Claims 1 and 4-8) under 35 U.S.C. § 102(b) as allegedly being anticipated by Granstrom *et al.* for reasons of record in light of the fact that the claims still had encompassed derived antigen compositions. Without comment on the merits of the rejection but to expedite matters, Applicants have amended the claims to specify the chemical inactivation of the whole cells and omit the subject matter drawn broadly to antigens derived from any *Sarcocystis neurona* source.

Applicants adopted, in essence, the kind recommendations of the Examiner by limiting the inactivated whole cells to chemically-inactivated *Sarcocystis neurona* cells and including new Claims 26-29 that are drawn to the specific merozoite antibody-inducing antigen derived from the single source comprising the deposited strain, *i.e.*, the *Sarcocystis neurona* isolate designated SNg, having ATCC Accession No. PTA-2972. In terms of the whole cell, Applicants teach on page 7, lines 28-31 of the specification that the *Sarcocystis neurona* isolate useful for the vaccine of the invention includes a variety of known strains SN1-6, UCD1-3 and the like. The novelty of the claimed invention is the chemical inactivation of the *S. neurona* whole cells to make a useful killed vaccine that can inoculate horses against the devastating equine protozoal myoencephalitis (EPM). While formalin is the preferred chemical agent illustrated in the working examples, Applicants disclose other chemicals that may be substituted for the formalin to achieve comparable results (see page 9, lines 23-29 of the specification). Clearly, the art does not teach or prepare formalin-inactivated cells, let alone any chemically-inactivated cells. Moreover, the art does not describe the specific antigen obtained from the deposited strain. Considering the Examiner's comments, it is believed that she will find that the claimed invention, as amended, is not anticipated by Granstrom *et al.* Consequently, Applicants respectfully ask that this rejection be withdrawn.

The Examiner also maintains the rejection of Claims 1, 2 and 4-7 (now Claims 1 and 4-7) under 35 U.S.C. § 102(b) as allegedly being anticipated by Liang *et al.* (1998) for reasons given

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on pages 8 and 9 of the Office action. To satisfy the Examiner's mandate for a structural difference between the claimed invention and the art, Applicants have amended the claims to recite the chemically-inactivated aspect of the whole cells and the specific antigens derived from the deposited strain that are not described by Liang *et al.* As such, Applicants respectfully request that the rejection be withdrawn.

The Examiner further maintains the rejection of Claims 1, 2, 5 and 8 (now Claims 1, 5 and 8) under 35 U.S.C. § 102(e) as allegedly being anticipated by Mansfield *et al.* (U.S. Patent No. 6,489,148) for reasons explained on pages 9-11 of the Office action. Owing to the present recitation of the chemically-inactivated whole cells and the specific antigens derived from the deposited strain, the heat-denatured cells of Mansfield *et al.* cannot be considered identical to the claimed invention. As a result, Applicants respectfully request that the rejection be withdrawn.

Lastly, the Examiner maintains the rejection of Claims 1, 2, 4-8 and 10-14 (now Claims 1, 4-8, 10, 11, 13 and 14) under 35 U.S.C. § 102(b) as allegedly being anticipated by Dubey *et al.* (J. Eukaryot. Microbiol., 1999) for reasons set forth on pages 11-14 of the Office action. Once more, the amendment of the claims to recite the chemically-inactivated whole cells sufficiently distinguishes the claimed invention from the art. Applicants respectfully ask that the rejection be withdrawn.

As the Examiner has appreciated, the art is full of many articles dealing with the diagnosis of EPM that is a highly prevalent and devastating disease in horses. The etiology appears to be clear but protection of the horses from getting the infection or disease is not. There is an overwhelming demand in the horse industry to find a viable vaccine that prevents or ameliorates this debilitating, neurological disease of horses. Applicants' *S. neurona* vaccine satisfies the art-recognized need to provide a useful vaccine that protects horses against EPM. It is plain to see that the claimed invention is novel.

If any outstanding issue remains in this case, the Examiner is invited to contact the undersigned attorney to discuss mutually agreeable solutions.

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Accordingly, it is believed that this application is now in condition for an allowance. Favorable treatment is respectfully urged.

Respectfully submitted,

WYETH

Date: May 3, 2006

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